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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,723	08/19/2002	Herve Geneste	51770	2695

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WOOD, PHILLIPS, KATZ, CLARK & MORTIMER
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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,723	GENESTE ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 April 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

1. Applicant's Preliminary Amendment, filed 4/4/02, has been entered.
Claims 1, 4 and 11 have been amended.
Claims 2-3 and 5-10 have been canceled.
Claims 1, 4 and 11 have been amended.

Claims 1, 4 and 11 are pending and under consideration in the instant application.

2. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ® or ™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

3. The filing date of the instant claims is deemed to be the filing date of PCT/EP00/09673, filed 10/2/00, as neither the foreign priority documents nor the translations of said foreign priority documents have been provided in the instant application.

Applicant's provision of the foreign priority documents to the International Bureau is acknowledged, however, the English translations have not been provided in the instant application. It is unclear whether the foreign priority document provides written description for the instant claims. Applicant is reminded that such priority for the instant limitations requires compliance with 35 U.S.C. 112, first paragraph.

4. 35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

5. Claims 1 and 3 are rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. § 101. See for example Ex parte Dunki , 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner,255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Given the lack of statutory basis for claims 1 and 4, the rest of this Office Action will be set forth with respect to claim 11 only in the interest of compact prosecution.

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. This is a rejection under 35 USC § 112, first paragraph, "written description".

Claim 11 is rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: "modulators of cytokine mediated signaling pathways or / and an integrin $\alpha_v\beta_3$ receptor antagonists"

The instant claims do not provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and structure. Since the disclosure fails to describe the common attributes or characteristics sufficiently that identify members of the genuses of "modulators of cytokine mediated signaling pathways or / and an integrin $\alpha_v\beta_3$ receptor antagonists", other than their ability to modulate or antagonize a "cytokine mediated signaling pathway or $\alpha_v\beta_3$".

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

In the absence of structural characteristics that are shared by members of the genuses of "modulators of cytokine mediated signaling pathways or / and an integrin $\alpha_v\beta_3$ receptor antagonists" based upon the general characteristics of modulators or antagonists, the skilled artisan would conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

8. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

In vitro and animal model studies have not correlated well with in vivo clinical trial results in patients. Since the therapeutic indices of immunosuppressive drugs or biopharmaceutical drugs can be species- and model-dependent, it is not clear that reliance on the ability of certain "cytokine mediated signaling pathways" and "integrin $\alpha_v\beta_3$ receptor antagonists" to treat certain conditions and certain diseases accurately reflects the relative ability or efficacy of the such "modulators" and / or "antagonists" to prevent disease.

For example, the diseases targeted by the modulators and antagonists of the claimed trade package are directed towards diseases such as autoimmune diseases (e.g. see pages 1 and 10 of the instant specification), which are diseases are diagnosed only after significant tissue damage has occurred. The skilled artisan would not predict that one could prevent such diseases.

Pharmaceutical therapies in the absence of in vivo clinical data are unpredictable for the following reasons; (1) the protein may be inactivated before producing an effect, i.e. such as proteolytic degradation, immunological inactivation or due to an inherently short half-life of the protein; (2) the protein may not reach the target area because, i.e. the protein may not be able to cross the mucosa or the protein may be adsorbed by fluids, cells and tissues where the protein has no effect; and (3) other functional properties, known or unknown, may make the protein unsuitable for in vivo therapeutic use, i.e. such as adverse side effects prohibitive to the use of such treatment. See page 1338, footnote 7 of Ex parte Aggarwal, 23 USPQ2d 1334 (PTO Bd. Pat App. & Inter. 1992).

In view of the lack of predictability of the art to which the invention pertains the lack of established clinical protocols for effective preventive therapies for diseases such as autoimmunity and the absence of objective evidence that "cytokine signaling pathway modulators" or "integrin $\alpha_v\beta_3$ receptor antagonists", undue experimentation would be required to practice the claimed products with a reasonable expectation of success, absent a specific and detailed description in applicant's specification of how to effectively practice the claimed products and absent working examples providing evidence which is reasonably predictive that the claimed products are effective for preventing diseases.

9. Claim 11 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is indefinite in its recitation because it is unclear whether the "trade package" can comprise a "cytokine signaling pathway modulators" separately from an "integrin $\alpha_v\beta_3$ receptor antagonists, given that the recitation appears to refer to the elements of the claim in both singularly and plural formats (e.g. "agent", "or / an", "together").

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

For examination purposes, the claimed trade package will be read as it reads on the trade package comprising either that "cytokine signaling pathway modulators" or an "integrin $\alpha_v\beta_3$ receptor antagonists" as well as their combination.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claim 11 is rejected under 35 U.S.C. § 102(e) as being anticipated by Wityak et al. (U.S. Patent No. 6,130,231) (see entire document).

Wityak et al. pharmaceutical kits using for treating thromboembolic disorders which comprise therapeutically effective amounts of the disclosed compounds as well as instructions for the administration of said compounds (see columns 76-77, overlapping paragraph). The utility of the disclosed compounds include their activity as "integrin $\alpha_v\beta_3$ receptor antagonists" (see Utility; columns 71-77). Further, it is noted these $\alpha_v\beta_3$ antagonists can be combination with a number of other inhibitors which would would have the inherent property of "cytokine signaling pathway modulators", as their activities include antiplatelet, anticoagulant and thrombin inhibitory properties (sees column 75 – 77). Therefore, Wityak et al. stands as prior art both on the claimed invention as it reads on comprising just an "integrin $\alpha_v\beta_3$ receptor antagonist", as well as its combination with "cytokine signaling pathway modulators". A species will anticipate a claim to a genus. See MPEP 2131.02.

12. Claim 11 is rejected under 35 U.S.C. § 102(e) as being anticipated by Thorpe et al. (U.S. Patent No. 6,887,468) (see entire document).

Thorpe et al. therapeutic kits including instructions comprising the described agents as well as combinations of said agents (e.g. see column 37, paragraph 1 and Therapeutic Kits on columns 101-102), wherein said agents include anti-VEGF antibodies, anti-VEGF receptor antibodies (see entire document) as well as a number of agents (see Detailed Description of the Invention, including, including certain anti-angiogenic inhibitors such as the LM609 antibodies which inhibits $\alpha_v\beta_3$ (e.g. see Anti-Angiogenics on columns 117 –124) for treating various conditions, including angiogenesis. Further, it is noted these anti-VEGF and anti-VEGF receptor antibodies which inhibit VEGF-mediated activities as well as other described therapeutic agents read on of "cytokine signaling pathway modulators" and certain anti-angiogenic agents such as the LM609 antibody read on "$\alpha_v\beta_3$ antagonists". Therefore, Thorpe et al. stands as prior art both on the claimed invention as it reads on comprising just an "cytokine signaling pathway modulator" as well as well as its combination with an "integrin $\alpha_v\beta_3$ receptor antagonist". A species will anticipate a claim to a genus. See MPEP 2131.02.

13. No claim allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 12, 2005